

K061682

**Attachment B:**  
**Summary of Safety and Effectiveness**  
*Prepared in accordance with 21 CFR Part 807.92(c).*

**JUL 12 2006**



**GE Healthcare**

General Electric Company  
P.O. Box 414, Milwaukee, WI 53201

**Section a):**

1. Submitter: GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC  
PO Box 414  
Milwaukee, WI 53201  
  
Contact Person: Allen Schuh,  
Manager, Safety and Regulatory Engineering  
Telephone: 414-721-3992; Fax: 414-721-3899  
  
Date Prepared: June 14, 2006
2. Device Name: GE Voluson E8 Diagnostic Ultrasound System  
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO  
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN  
Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX
3. Marketed Device: GE Voluson 730 Diagnostic Ultrasound System - K003525, K032620, K041688  
A device currently in commercial distribution.
4. Device Description: The Voluson E8 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 57 cm wide, 96 cm deep and 149 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 10 inch LCD touch screen and color 15 inch LCD image display. This modification will provide users with additional probe options, improved user interface and overall quality and image enhancement.
5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal/OB; Abdominal (including GYN, pelvic and infertility monitoring/follicle development); Pediatric; Small Organ (breast, testes, thyroid etc.); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Musculo-skeletal Conventional and Superficial; Peripheral Vascular; Transvaginal (TV); Transrectal (TR); and Intraoperative (abdominal, PV and neurological).
6. Comparison with Predicate Devices: The GE Voluson E8 is of a comparable type and substantially equivalent to the current GE Voluson 730 Pro/Expert. It has the same technological characteristics, key safety and effectiveness features, and is similar in physical design, construction and materials and has the same intended uses and basic operating modes as the predicate device.

**Section b):**

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
2. Clinical Tests: None required.
3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE Voluson E8 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 12 2006

Mr. Allen Schuh  
Manager, GE Ultrasound Product Safety  
and Regulatory Engineering  
GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC  
9900 Innovation Drive  
WAUWATOSA WI 53226

Re: K061682

Trade Name: GE Voluson E8 Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulation Number: 21 CFR 892.1570  
Regulation Name: Diagnostic ultrasonic transducer  
Regulatory Class: II  
Product Code: IYN, IYO, and ITX  
Dated: June 14, 2006  
Received: June 15, 2006

Dear Mr. Schuh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Voluson E8 Ultrasound System, as described in your premarket notification:



*Protecting and Promoting Public Health*

Transducer Model Number

<u>RAB2-5-D</u>	<u>IC5-9-D</u>	<u>9L-D</u>
<u>RAB4-8-D</u>	<u>PA6-8-D</u>	<u>M12LW</u>
<u>RIC5-9-D</u>	<u>SP10-16-D</u>	<u>3S-D</u>
<u>RNA5-9-D</u>	<u>RSP6-16-D</u>	<u>P2D</u>
<u>RRE6-10-D</u>	<u>RIC6-12-D</u>	<u>P6D</u>
<u>AB2-7-D</u>	<u>RAM3-8</u>	<u>M6C</u>
<u>4C-D</u>	<u>RSM5-14</u>	<u>11L-D</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

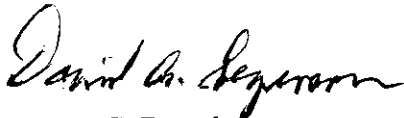
Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Ewa Czerska at (301) 594-1212.

Sincerely yours,

  
*for*

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

## Attachment E

### *Indications for Use Forms*

The following forms represent indications with clinical applications and exam types along with the modes of operation for the **Voluson E8** system and for all of its probe/mode combinations. Combinations identified by "N" are new while "P" represents those previously cleared with the unmodified Voluson 730. In a similar manner, "E" represents combinations added to the unmodified Voluson 730 via Appendix E of the 510(k) Guidance. The subject modification does not alter the previously cleared system level indications, clinical applications or modes of operation.

## Diagnostic Ultrasound Indications for Use Form

### GE Voluson E8 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P	E	P	P	P	P	P	P	[5,6]
Abdominal <sup>[1]</sup>	P	P	P	P	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	E	P	P	P	P	P	P	[5,6]
Small Organ <sup>[2]</sup>	P	P	P	E	P	P	P	P	P	P	[5,6]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	P	[5]
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[5,6]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6]
Transurethral											
Intraoperative	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological	P	P	P		P	P	P	P	P	P	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic.

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Adult and Pediatric.

[5] 3D/4D Imaging Mode.

[6] Includes imaging of guidance of biopsy (2D/3D/4D).

[7] Includes infertility monitoring of follicle development.

[8] Includes urology/prostate.

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number       K061682

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson E8 with RAB2-5-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[5] 3D/4D Imaging Mode

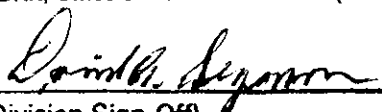
[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number       K061682      

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson E8 with RAB4-8-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Pediatric	E	E	E		E	E	E	E	E	E	[5,6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology

[5] 3D/4D Imaging Mode

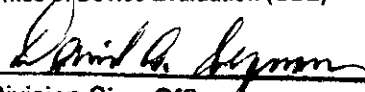
[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number       K061682      

Prescription User (Per 21 CFR 801.109)

### Diagnostic Ultrasound Indications for Use Form

#### GE Voluson E8 with RIC5-9-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal <sup>[8]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal	P	P	P		P	P	P	P	P	P	[5,6]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
 and Radiological Devices

Prescription User (Per 21 CFR 801.109)

510(k) Number

12061682

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson E8 with RNA5-9-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P	E	P	P	P	P	P	P	[5,6]
Abdominal <sup>[1]</sup>	P	P	P	E	P	P	P	P	P	P	[5,6]
Pediatric	P	P	P	E	P	P	P	P	P	P	[5,6]
Small Organ <sup>[2]</sup>	P	P	P	E	P	P	P	P	P	P	[5,6]
Neonatal Cephalic	P	P	P	E	P	P	P	P	P	P	[5]
Adult Cephalic											
Cardiac <sup>[3]</sup>	P	P	P	E	P	P	P	P	P	P	[5]
Peripheral Vascular	P	P	P	E	P	P	P	P	P	P	[5,6]
Musculo-skeletal Conventional	P	P	P	E	P	P	P	P	P	P	[5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal is Neonatal and pediatric

[2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[3] Cardiac is Neonatal and Pediatric.

[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number

Prescription User (Per 21 CFR 801.109)

### Diagnostic Ultrasound Indications for Use Form

#### GE Voluson E8 with RRE6-10-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal <sup>[6]</sup>	P	P	P		P	P	P	P	P	P	[5,6]
Transvaginal	E	E	E		E	E	E	E	E	E	[5,6]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[8] Includes urology/prostate

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson E8 with AB2-7-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	P	P	P		P	P	P	P	P	P	[6]
Pediatric	P	P	P		P	P	P	P	P	P	[6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	[6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology

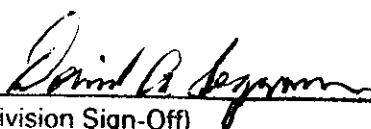
[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)

Division of Reproductive, Abdominal,  
 and Radiological Devices

510(k) Number

K061682

Prescription User (Per 21 CFR 801.109)

### Diagnostic Ultrasound Indications for Use Form

#### GE Voluson E8 with 4C-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P	E	P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>	P	P	P	E	P	P	P	P	P	P	[6]
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	P	P	P	E	P	P	P	P	P	P	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology

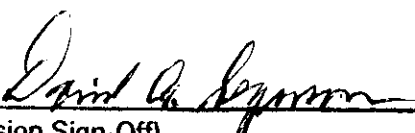
[6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
 510(k) Number 2061682

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson E8 with IC5-9-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	P	P	P		P	P	P	P	P	P	[6]
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal <sup>[8]</sup>	P	P	P		P	P	P	P	P	P	[6]
Transvaginal	P	P	P		P	P	P	P	P	P	[6]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [6] Includes imaging of guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal,  
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510(k) Number

Prescription User (Per 21 CFR 801.109)

### Diagnostic Ultrasound Indications for Use Form

#### GE Voluson E8 with PA6-8-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>	E	E	E	E	E	E	E	E	E	E	
Pediatric	E	E	E	E	E	E	E	E	E	E	
Small Organ <sup>[2]</sup>											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac <sup>[3]</sup>	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other <sup>[4]</sup>											
Exam Type, Means of Access											
Transesophageal											
Transrectal <sup>[6]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

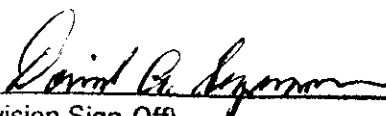
Notes: [1] Abdominal is Neonatal , pediatric and obstetrics

[3] Cardiac is Adult and Pediatric.

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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 510(k) Number K061682

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson E8 with SP10-16-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	E	E	E		E	E	E	E	E	E	[6]
Small Organ <sup>[2]</sup>	P	P	P		P	P	P	P	P	P	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	E	E	E		E	E	E	E	E	E	[6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	[6]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

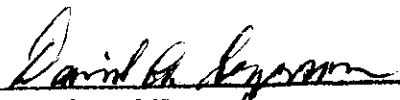
Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[6] Includes imaging of guidance of biopsy (2D)

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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510(k) Number K061682

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson E8 with RSP6-16-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	E	E	E		E	E	E	E	E	E	[5,6]
Small Organ <sup>[2]</sup>	E	E	E		E	E	E	E	E	E	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	E	E	E		E	E	E	E	E	E	[5,6]
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	[5,6]
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E	E	[5,6]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal <sup>[8]</sup>											
Transvaginal											
Transurethral											
Intraoperative	E	E	E		E	E	E	E	E	E	
Intraoperative Neurological	E	E	E		E	E	E	E	E	E	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients


[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson E8 with RIC6-12-D Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	E	E	E		E	E	E	E	E	E	[5,6]
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal <sup>[8]</sup>	E	E	E		E	E	E	E	E	E	[5,6]
Transvaginal	E	E	E		E	E	E	E	E	E	[5,6]
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

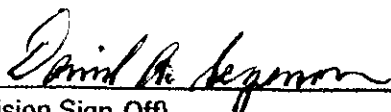
[7] Includes infertility monitoring of follicle development

[8] Includes urology/prostate

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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### Diagnostic Ultrasound Indications for Use Form

#### GE Voluson E8 with RAM3-8 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	N	N	N		N	N	N	N	N	N	[ 5,6]
Abdominal <sup>[1]</sup>	N	N	N		N	N	N	N	N	N	[ 5,6]
Pediatric	N	N	N		N	N	N	N	N	N	[ 5,6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	[ 5,6]
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology

[5] 3D/4D Imaging Mode

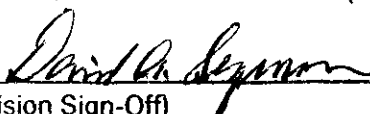
[6] Includes imaging of guidance of biopsy (3D/4D)

[7] Includes infertility monitoring of follicle development

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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510(k) Number 2061682

**Diagnostic Ultrasound Indications for Use Form**  
**GE Voluson E8 with RSM5-14 Transducer**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	N	N	N		N	N	N	N	N	N	[5,6]
Small Organ <sup>[2]</sup>	N	N	N		N	N	N	N	N	N	[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	[5,6]
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	[5,6]
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	[5,6]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

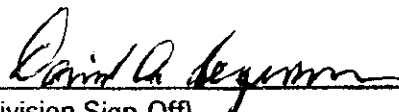
[5] 3D/4D Imaging Mode

[6] Includes imaging of guidance of biopsy (3D/4D)

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

### GE Voluson E8 with 9L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	N	N	N		N	N	N	N	N	N	[6]
Small Organ <sup>[2]</sup>	N	N	N		N	N	N	N	N	N	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	[6]
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	[6]
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

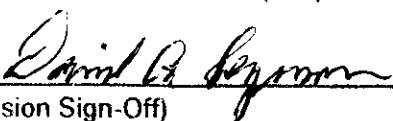
Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[6] Includes imaging of guidance of biopsy (2D)

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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 510(k) Number K061682

Prescription User (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

### GE Voluson E8 with M12LW Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	E	E	E		E	E	E	E	E	E	[6]
Small Organ <sup>[2]</sup>	E	E	E		E	E	E	E	E	E	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	E	E	E		E	E	E	E	E	E	[6]
Musculo-skeletal Conventional	E	E	E		E	E	E	E	E	E	[6]
Musculo-skeletal Superficial	E	E	E		E	E	E	E	E	E	[6]
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[6] Includes imaging of guidance of biopsy (2D)

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*David B. Leggett*  
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Division of Reproductive, Abdominal,  
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510(k) Number

*K061682*

Prescription User (Per 21 CFR 801.109)

### Diagnostic Ultrasound Indications for Use Form

#### GE Voluson E8 with 3S-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	N	N	N	N	N	N	N	N	N	N	
Abdominal <sup>[1]</sup>	N	N	N	N	N	N	N	N	N	N	
Pediatric	N	N	N	N	N	N	N	N	N	N	
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	
Cardiac <sup>[3]</sup>	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic

[3] Cardiac is adult and Pediatric

[7] Includes infertility monitoring of follicle development

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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510(k) Number

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### Diagnostic Ultrasound Indications for Use Form

#### GE Voluson E8 with P2D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

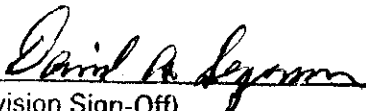
Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic				N							
Cardiac <sup>[3]</sup>				N							
Peripheral Vascular				N							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is adult and Pediatric

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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510(k) Number K061682

### Diagnostic Ultrasound Indications for Use Form

#### GE Voluson E8 with P6D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

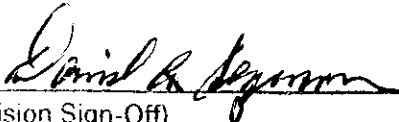
Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric											
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>				N							
Peripheral Vascular				N							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [3] Cardiac is adult and Pediatric

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Prescription User (Per 21 CFR 801.109)

510(k) Number

2061682

### Diagnostic Ultrasound Indications for Use Form

#### GE Voluson E8 with M6C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>	N	N	N	N	N	N	N	N	N	N	[6]
Abdominal <sup>[1]</sup>	N	N	N	N	N	N	N	N	N	N	[6]
Pediatric	N	N	N	N	N	N	N	N	N	N	[6]
Small Organ <sup>[2]</sup>											
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes renal, GYN/Pelvic, Urology


[6] Includes imaging or guidance of biopsy (2D)

[7] Includes infertility monitoring of follicle development

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices

Prescription User (Per 21 CFR 801.109)

510(k) Number

K061682

## Diagnostic Ultrasound Indications for Use Form

### GE Voluson E8 with 11L-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics <sup>[7]</sup>											
Abdominal <sup>[1]</sup>											
Pediatric	N	N	N		N	N	N	N	N	N	[6]
Small Organ <sup>[2]</sup>	N	N	N		N	N	N	N	N	N	[6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac <sup>[3]</sup>											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	[6]
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	[6]
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	[6]
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid, salivary gland, lymph nodes, pediatric and neonatal patients

[6] Includes imaging of guidance of biopsy (2D)

[\*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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